

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1057020	(X3) Date Survey Completed 06/24/2024
Name of Provider or Supplier Skin Md, Llc	Street Address, City, State 16105 S Lagrange Rd, Orland Park, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5006	<p>MYCOLOGY CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM); the laboratory failed to meet the requirements specified for mycology testing in 2023 and 2024, affecting nine patient test results. Findings include: 1. The laboratory failed to document the required procedure manual items not provided by the manufacturer's "Remel Intended Use" insert for the mycology test Dermatophyte Test Medium (DTM), affecting nine of nine patient test results (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. (Refer to D5405). 2. The laboratory failed to follow the manufacturer's instructions for mycology test Dermatophyte Test Medium (DTM) in 2023, affecting seven of eight DTM patent tests (DTM PT 1 - 4 and DTM PT 6 - 8). (Refer to D5411). 3. The laboratory failed to verify the performance specifications for the mycology test procedure Dermatophyte Test Medium (DTM) prior to patient testing (DTM PT) in 2023 and 2024, affecting nine of nine patient test results (DTM PT - 1 through DTM PT - 9). (Refer to D5421). 4. The laboratory failed to document positive and negative quality control materials for the mycology qualitative test procedure Dermatophyte Test Medium (DTM) for nine of nine patient test dates (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. (Refer to D5449). 5. The laboratory failed to check each batch of Dermatophyte Test Medium (DTM) for the ability to select specific organisms and produce a biochemical response prior to the initial use of DTM for nine of nine patient tests (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. (Refer to D5477).</p>
D5405	PROCEDURE MANUAL

CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM); the laboratory failed to document the required procedure manual items not provided by the manufacturer's "Remel Intended Use" insert for the mycology test Dermatophyte Test Medium (DTM), affecting nine of nine patient test results (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. Findings include: 1. Review of the manufacturer's "Remel Intended Use" insert for the DTM mycology test revealed no documentation of all of the required procedure manual items listed in the State Operations Manual (SOM) - Appendix C Standard 493.1251. Documentation is required for the following items: a) Patient preparation, specimen collection, labeling, storage, preservation, transportation, and criteria for specimen acceptability and rejection. b) Step - by - step performance of the procedure and interpretation of results. c) Preparation of controls, reagents, and other materials used in testing. d) The reportable range for test results as established or verified. e) Control procedures. f) Corrective action to take when control results fail. g) Imminently life-threatening test results, panic or alert values. h) The laboratory's system for entering results in the patient records and reporting patient results; the protocol for reporting life threatening results, panic, or alert values. 2. Review of the "Skin MD LLC DTM Log" revealed nine patients tested for the following dates: a. DTM PT - 1 Date: 02/18/2023 Location: right anterior neck b. DTM PT - 2 Date: 04/27/2023 Location: scalp c. DTM PT - 3 Date: 05/09/2023 Location: L distal thigh d. DTM PT - 4 Date: 06/23/2023 Location: right scalp e. DTM PT - 5 Date: 07/12/2023 Location: right posterior thigh f. DTM PT - 6 Date: 08/28/2023 Location: right scalp g. DTM PT - 7 Date: 09/12/2023 Location: right and left buttocks h. DTM PT - 8 Date: 09/19/2023 Location: Left inferior lateral back i. DTM PT - 9 Date: 02/19/2024 Location: Left ulnar palm 3. On 06/24/2024, at 2:20 p.m., the LM confirmed the above findings.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, manufacturer's instructions and interview with the laboratory manager (LM); the laboratory failed to follow the manufacturer's instructions for mycology test Dermatophyte Test Medium (DTM) in 2023, affecting seven of eight DTM patent tests (DTM PT 1 - 4 and DTM PT 6 - 8). Findings Include: 1. Review of the manufacturer's "Remel Intended Use" insert for the DTM mycology test revealed the following information: " Procedure... 4. Incubate in ambient air at 25-30 degrees C for up to 14 days." 2. Review of the "Skin MD LLC DTM Log" revealed seven of eight DTM PT cultures were incubated beyond the manufacturer's

instructions of 14 days in 2023. a. DTM PT - 1 Log Date: 02/18/2023 Test Result Date: 03/14/2023 b. DTM PT - 2 Log Date: 04/27/2023 Test Result Date: 05/15/2023 c. DTM PT - 3 Log Date: 05/09/2023 Test Result Date: 05/30/2023 d. DTM PT - 4 Log Date: 06/23/2023 Test Result Date: 07/29/2023 e. DTM PT - 5 Log Date: 07/12/2023 Test Result Date: 07/18/2023 f. DTM PT - 6 Log Date: 08/28/2023 Test Result Date: 09/25/2023 g. DTM PT - 7 Log Date: 09/12/2023 Test Result Date: 10/03/2023 h. DTM PT - 8 Log Date: 09/19/2023 Test Result Date: 10/01/2023 3. On 06/24/2024, at 2:20 p.m., the LM confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM); the laboratory failed to verify the performance specifications for the mycology test procedure Dermatophyte Test Medium (DTM) prior to patient testing (DTM PT) in 2023 and 2024, affecting nine of nine patient test results (DTM PT - 1 through DTM PT - 9). Findings include: 1. Review of laboratory records revealed no documentation for the verification of the performance specifications for the "Remel" DTM mycology test procedure prior to patient testing in 2023 and 2024, affecting nine of nine patient test results (DTM PT - 1 through DTM PT - 9). 2. Review of the "Skin MD LLC DTM Log" revealed nine patients tested for the following dates: a. DTM PT - 1 Date: 02/18/2023 Location: right anterior neck b. DTM PT - 2 Date: 04/27/2023 Location: scalp c. DTM PT - 3 Date: 05/09/2023 Location: L distal thigh d. DTM PT - 4 Date: 06/23/2023 Location: right scalp e. DTM PT - 5 Date: 07/12/2023 Location: right posterior thigh f. DTM PT - 6 Date: 08/28/2023 Location: right scalp g. DTM PT - 7 Date: 09/12/2023 Location: right and left buttocks h. DTM PT - 8 Date: 09/19/2023 Location: Left inferior lateral back i. DTM PT - 9 Date: 02/19/2024 Location: Left ulnar palm 3. On 06/24/2024, at 12:30 p.m., the LM confirmed the above findings.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM); the laboratory failed to document positive and negative

quality control materials for the mycology qualitative test procedure Dermatophyte Test Medium (DTM) for nine of nine patient test dates (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. Findings include: 1. Review of the "Remel Intended Use" insert revealed the following information: "QUALITY CONTROL ...Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported." 2. Review of laboratory records revealed two DTM PT reported in 2023: a. DTM - PT 1 MRN: MM0000000494 DATE TESTED: 02/18/2023 DATE RESULTED: 03/14/2023 - DTM NEGATIVE b. DTM - PT 3 MRN: NEX347561 DATE TESTED: 05/09/2023 DATE RESULTED: 05/30/2023 - Tinea Corporis 3. Review of the "Skin MD LLC DTM Log" revealed an additional seven test dates recorded for DTM patient testing (DTM - PT): a. DTM PT - 2 Date: 04/27/2023 Location: scalp b. DTM PT - 4 Date: 06/23/2023 Location: right scalp c. DTM PT - 5 Date: 07/12/2023 Location: right posterior thigh d. DTM PT - 6 Date: 08/28/2023 Location: right scalp e. DTM PT - 7 Date: 09/12/2023 Location: right and left buttocks f. DTM PT - 8 Date: 09/19/2023 Location: Left inferior lateral back g. DTM PT - 9 Date: 02/19/2024 Location: Left ulnar palm 4. Review of laboratory records revealed no documentation for the positive and negative quality control materials utilized for the qualitative test procedure DTM for nine of nine patient test dates in 2023 and 2024. 5. On 06/24/2024, at 2:20 p.m., an interview with the LM revealed, "No quality control was recorded for the DTM testing dates".

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM); the laboratory failed to check each batch of Dermatophyte Test Medium (DTM) for the ability to select specific organisms and produce a biochemical response prior to the initial use of DTM for nine of nine patient tests (DTM PT - 1 through DTM PT - 9) in 2023 and 2024. Findings include: 1. Review of the "Skin MD LLC DTM Log" revealed nine patients tested for the following dates: a. DTM PT - 1 Date: 02/18/2023 Location: right anterior neck b. DTM PT - 2 Date: 04/27/2023 Location: scalp c. DTM PT - 3 Date: 05/09/2023 Location: L distal thigh d. DTM PT - 4 Date: 06/23/2023 Location: right scalp e. DTM PT - 5 Date: 07/12/2023 Location: right posterior thigh f. DTM PT - 6 Date: 08/28/2023 Location: right scalp g. DTM PT - 7 Date: 09/12/2023 Location: right and left buttocks h. DTM PT - 8 Date: 09/19/2023 Location: Left inferior lateral back i. DTM PT - 9 Date: 02/19/2024 Location: Left ulnar palm 2. Review of laboratory records revealed no documentation of DTM batch testing records for the ability to select specific organisms and produce a biochemical response prior to the initial use of DTM for nine of nine patient tests in 2023 and 2024. 3. On 06/24/2024, at 2:20 p.m., the LM confirmed the above findings.